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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------------------|------------------|
| 10/505,232 | 04/18/2005 | Orde Levinson | 23590 | 3885 |
| 24932 7590 01/10/2008 LAUBSCHER & LAUBSCHER, P.C. 1160 SPA ROAD SUITE 2B ANNAPOLIS, MD 21403 | | | EXAMINER FOREMAN, JONATHAN M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |
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| | | | 01/10/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/505,232

Applicant(s)

LEVINSON, ORDE

Examiner

Jonathan ML Foreman

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/22/07.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/22/07 has been entered

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 – 8 and 10 - 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lofley et al. (WO 90/13280) in view of U.S. Patent No. 4,252,132 to Kuntz.

In regard to claims 1 – 8 and 10 - 16, Lofley et al. shows a urine collection device including a urine receptor a rim (13) defining inlet area (11), an elongate tubular member (12) extending to an open end from receptor outlet aperture (14) with opening formed in the sidewall (near 102 of Figure 1) of the tubular member (12), a coupling means (18) for releasably mounting a urine collection container. However, Lofley et al. fail to disclose a flow director located within the tubular member, the flow director defining the opening at a raised elevation relative to a surface of the side of the tubular member and formed to direct urine past the opening. Kuntz discloses a urine receptor having a flow director defining the opening at a raised elevation relative to a surface of the side of

the tubular member and formed to direct urine past the opening (70; Col. 2, lines 25 – 42). The flow director includes a projection along the member (Figure 3). The projection is provided upstream and downstream of the opening (Figure 3). The projection upstream the opening as a surface inclined relative to the surface of the member (Figure 3). Kuntz discloses the projection including a wall that extends across the member corresponding to the upstream edge of opening (Figure 4). The flow director is formed to channel the urine flow along either side of the aperture. Kuntz teaches the coupling means including a passage extending therethrough that meets the opening to present an area from which air in the collection container can escape into the tubular member. The passage of the coupling means extends into the member by an amount that is greater than the first passage. Kuntz teaches a covering means (60) provided adjacent the opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coupling means disclosed by Lofley et al. to include the coupling means having a flow director as taught by Kuntz in order to isolate and collect contaminant-free urine from a patient (Col. 2, lines 20 – 21). cap adjacent the opening.

4. Claims 17 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lofley et al. (WO 90/13280) in view of U.S. Patent No. 4,252,132 to Kuntz as applied to claims 1 above, and further in view of Gordon (4494581) embodiment of Figure 4.

Lofley et al. in view of Kuntz shows a device for urine collection but lacks a flow limiter comprising a valve and a closure member comprising a ball. In regard to claims 17-19, Gordon teaches a device for urine collection including a flow limiter 50 in the form of a movable valve, contained in collection container 54 that expands when a predetermined amount of urine is collected in the container and closes the valve of the container (column 3, lines 9-23). In regard to claims 20-22, Gordon teaches a closure member 51 in the form of a hollow sphere positioned between the

upper and lower openings capable of closing the upper opening (Figure 4 column 3 lines 20-32) and possesses a density lower than urine. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Lofley et al. in view of Kuntz with a flow limiter comprising a valve and a closure member comprising a ball as taught by Gordon since such modification would provide an indicator that a predetermined volume of urine was collected and a closure unit less dense than urine to inhibit further flow of urine into the collection container.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lofley et al. (WO 90/13280) in view of U.S. Patent No. 4,252,132 to Kuntz.

In regard to claim 9, Lofley et al. in view of Kuntz disclose the coupling means extending into the tubular member, but fail to disclose the height being between 20% and 60% of the internal dimension of the tubular member. However, a change in the size of a prior art device is a design consideration within the skill of the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the height of the coupling means to be between 20% and 60% or any height as desired in order to allow more or less initial urine flow to bypass the urine collection container.

Response to Arguments

6. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

Application/Control Number:
10/505,232
Art Unit: 3736

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JMLF

